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The WINPack 1 a novel wearable system for heart rate and vital signs monitoring

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Abstract

This paper presents a modular device for remote multi-parametric health monitoring, the WINPack system, which consists in a wearable acquisition unit with limited dimension (85x55x25 mm) to which six different sensor modules (35x25x25 mm), and a signal communication management module (32x23x10 mm) can be connected. Modularity, patented self-configurability, wearability and wireless communication are key characteristics of the WINPack system which can optimize the use of personal monitoring devices inside hospitals and at home. Thanks to these important features, each required module can be added to the system by simply connecting it to the central acquisition unit. The present paper shows the results of preclinical tests performed with the first release of the WINPack system, the WINPack1, equipped with basic modules for monitoring of body temperature, body posture, heart rate and with a Bluetooth communication module.

Keywords: wireless monitoring, heart rate, chronic patients.

1. Introduction

It was estimated that remote health monitoring systems could help to reduce the global increase in the cost of health care related to the world aging [1]. Nevertheless those systems are not yet so widespread in the hospital wards, because of their limited applicability in different use case models. Three categories of wireless monitoring devices can be defined: 1) small wearable systems with fixed single or multiple functionalities [2], or 2) portable systems whose configuration can be modified and updated only by accessing to the hardware components [3],[4]. Thanks to its patented self configurability characteristic, the WINPack system is able to overcome the limits of the other systems which make it usable in different clinical contexts, by simply changing the modules connected to the system central unit. The first release of the WINPack system, WINPack1 from WIN s.r.l. (www.winmed.it, Italy), includes: the acquisition unit, a

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rechargeable battery, a proprietary battery charger, and three sensor modules for monitoring body temperature (T), body posture, and I lead electrocardiogram (ECG), as shown in Figure 1.

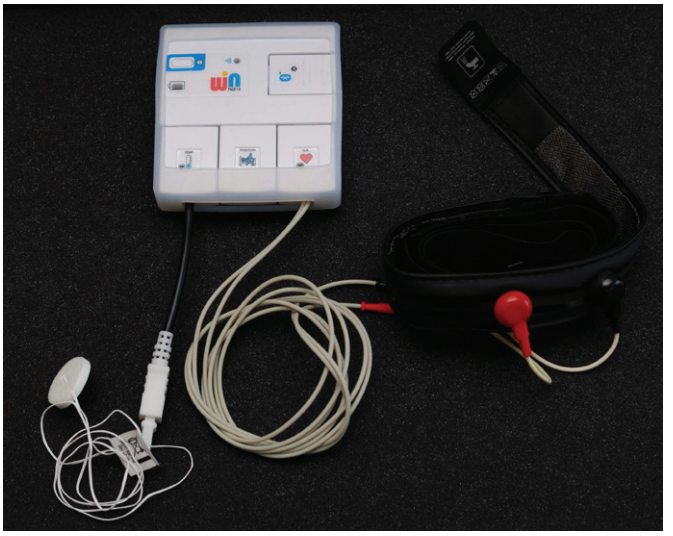

Fig. 1: WINPack1 with the connected sensor modules.

Moreover the system includes high performance CE certified commercial sensors which consist in: a thoracic band for fixing the ECG electrodes (Polar) and superficial probe (including a biomedical thermistor) for skin temperature measurement (Smiths Medical).

Signals coming from the sensor modules are evaluated and thus wirelessly transmitted to a PC station, by Bluetooth Class 1 communication. The WINPack1 system has successfully passed the electrical and EMC security testing required for system CE certification. Extensive pre-clinical tests were also performed on the system prototype, on 5 able-bodied subjects, comparing the ECG and temperature module functionalities with standard systems. The present paper describes results of trials performed on the hearth rate (in two different conditions) and on the temperature module.

2. Preclinical tests: methods and results

The accuracy of the signals acquired from the ECG/heart rate and temperature modules was evaluated by comparative tests performed with the Easy ECG Pocket (Ates Medica Device S.r.l., http://www.atesdevice.it), as standard wired system, and VedoEco thermometer (Pic Indolor, Artsana, http://www.picsolution.com).

Subjects were asked to wear the two systems at the same time, WINPack1 onto the provided belt at the waist, with the thoracic band on the chest under the breast, and positioning the three ECG electrodes of the Ates system, 2 directly below the thoracic band and the third reference electrode on the right ankle. The acquisition from the two systems was syncronously activated and signals were recorded for 24 seconds. Tests were repeated in basal (subject sitting in relaxed condition) and walking (subject walking at natural constant speed) conditions. Trials were repeated five times on each subject, for each experimental condition.

Post-processing and statistical analysis of the recorded signals were performed by custom MATLAB scripts (MathWorks, Inc., Natick, MA, USA), extracting the Heart Rate (HR) in bpm by the ECG trajectories. A high correlation between the measurements obtained with the 2 systems was found

(ρ=0.997 and ρ=0.994 in basal and walking conditions respectively) with a mean percentage error of the WINPack1 HR measurements with respect to the standard ones of 1.6% and 4.1% in basal and walking conditions respectively. Least squares algorithm was employed for extracting the linear regression between the two systems (Fig. 3 and 4-right).

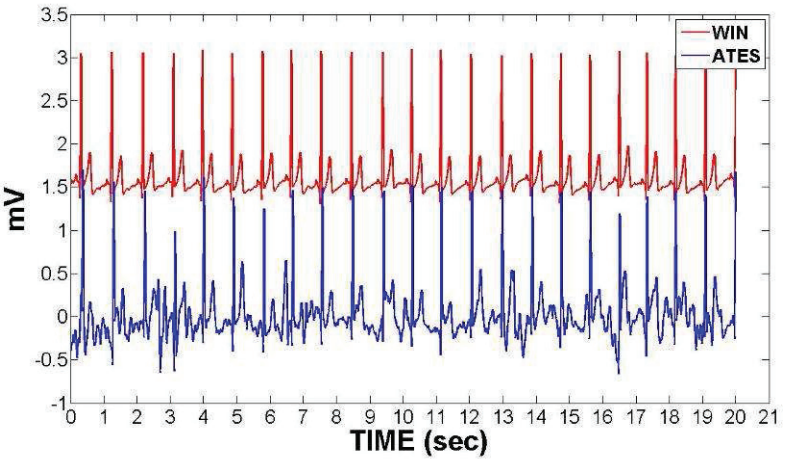

Fig. 2: ECG synchronized signals acquired by WIN (red line) and ATES (blue line) systems.

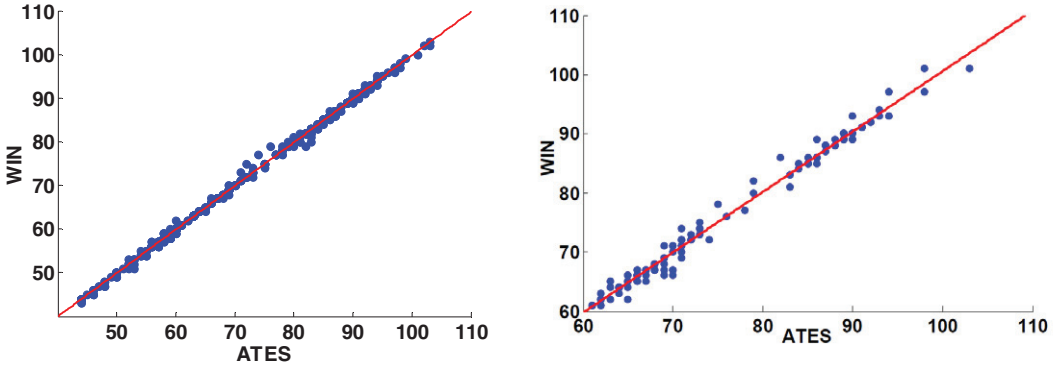

Fig. 3: Linear regression between ATES and WINPack1 heart rate readings in basal condition (left), a=1, b=-0.17 and walking condition (right), a=1, b=-1.5.

For temperature (T) tests, subjects were asked to wear the WINPack1 central unit on the waist with the connected T module, attaching the probe close to the axillary arteria. The mean value of settling time (computed as the time in which the measured value reaches the steady state with a tolerance error of 0.2°C) of the WINPack1 was about δ=7 min. The temperature provided with the WINPack1 probe at the beginning of the acquisition was equal to room temperature. The mean percentage error of the WINPack1 T measurements, compared with those obtained by a standard thermometer (5 times on each subject in basal condition for 30 sec under the same axilla in close proximity of the WINPack1 temperature probe), was equal to 0.2%. The correlation between the two measures was ρ=0.8915. This value cannot be compared with the PIC system since it is not designed for continous measurement of temperature and it has a lower resolution, thus presenting a shorter time for providing the final value of temperature.

The battery module duration was also evaluated through a consumption test, showing that the device guarantees 11 hours of work continuously transmitting the data recorded by all the connected sensors to a main receiving station at 10 m distance.

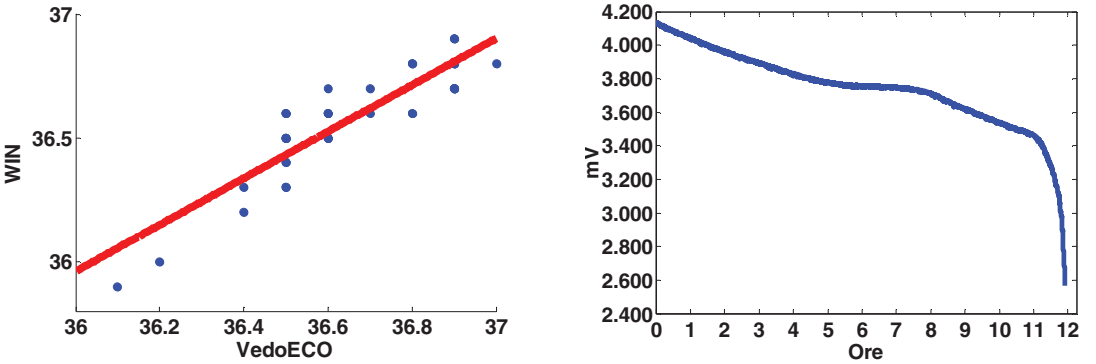

Fig. 4: Linear regression between VedoECO and WINPack1 temperature measures (climbing stairs), a=0.94, b=2.1 (left); Measured discharge profile of WINPack battery (right).

3. Discussions and Conclusions

Tests results evidenced the high reliability of heart rate and temperature module readings. The correlation of the WINPack1 measures with the standard systems, and relative linear regressions coefficients, were optimal for T measure (r=0.8915) and for HR measure, in basal (r=0.997) and walking (r=0.994) conditions. More details on the ECG signal reliability are required, in order to evaluate performance of the device during movements of the patient. Several alternative devices (wired\wireless) will be considered for assessing the stability of WINPack system in continuous recording and in non-basal conditions, in order to better recreate the possible use cases and scenarios.

Further tests will be required for evaluating the effect on the energy consumption related to the used communication modules (i.e. Bluetooth Class 1) of the distance between user and main station.

Clinical extensive trials are starting in order to assess the effectiveness, usability, and acceptability of the system from the user and patient point of views.

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